

ATTY. DOCKET NO. 00166.0051-005

APPLICATION NO. 09/578,908

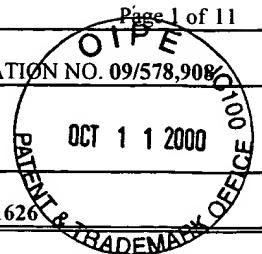
APPLICANT Mesens et al.

OCT 11 2000

FILING DATE May 26, 2000

GROUP 1626

**FORM PTO-1449**  
**INFORMATION DISCLOSURE STATEMENT**



## U.S. PATENT DOCUMENTS

EXAMINER INITIALS	REF. NO.	DOCUMENT NUMBER	GRANT DATE	NAME	CLASS	SUB-CLASS	FILING DATE
ES	AA1	3,197,180	07/1965	Bates et al.	5	—	
	AB1	3,523,906	08/1970	Vrancken et al.			
	AC1	3,691,090	09/1972	Kitajima et al.			
	AD1	3,737,337	06/1973	Schnoring et al.			
	AE1	3,773,919	11/1973	Boswell et al.			
	AF1	3,891,570	06/1975	Fukushima et al.			
	AG1	3,923,288	12/1976 05	King et al.			
	AH1	3,960,757	06/1976	Morishita et al.			
	AI1	4,034,965	07/1977	King et al.			
	AJ1	4,111,402	09/1978	Barbini et al.			
BS	AK1	4,128,641	12/1978	Itil et al.	—	—	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS	REF. NO.	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
ES	AL1	1 212 730	11/1970	United Kingdom	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No
	AM1	1 351 811	03/1974	United Kingdom	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No
	AN1	2 015 360	09/1979	United Kingdom	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No
	AO1	0 052 510	05/1982	Europe	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No
BS	AP1	0 071 454	02/1983	Europe	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No

EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)					
BS	AS 1	Abstract of WO 94/10982, Kino et al., "Sustained-release Microspheres Requiring No Surgical Implant - Contains Hydrophobic Antipsychotic Encapsulated in Biodegradable Polymer, Allowing Prolonged Therapeutic Effect by Infrequent Administration". (1994)					
BS	AT 1	Baker, J.R., "Motionless Mixers Stir Up New Uses," <i>Chemical Engineering Progress</i> : 32-38 (June 1991).					

EXAMINER

*Shenoda & clay*

DATE CONSIDERED

*10/22/01*

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EXAMINER INITIALS		DOCUMENT NUMBER	GRANT DATE	NAME	CLASS	SUB-CLASS	FILING DATE
ES	AA2	4,201,482	05/1980	Imhauser et al.	—	—	
	AB2	4,208,136	06/1980	King et al.	—	—	
	AC2	4,329,331	05/1982	Kallick et al.	—	—	
	AD2	4,335,127	06/1982	Vandenberk et al.	—	—	
	AE2	4,337,261	06/1982	Shutske et al.	—	—	
	AF2	4,324,870	08/1982	Kennis et al.	—	—	
	AG2	4,352,811	10/1982	Strupczewski	—	—	
	AH2	4,389,330	06/1983	Tice et al.	—	—	
	AI2	4,443,451	04/1984	Kennis et al.	—	—	
	AJ2	4,458,076	07/1984	Strupczewski	—	—	
ES	AK2	4,485,107	11/1984	Kennis et al.	—	—	

## FOREIGN PATENT DOCUMENTS

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	AN2	0 195 450	09/1986	Europe	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No
	AO2	0 196 132	10/1986	Europe	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No
ES	AP2	0 248 531	12/1987	Europe	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No

EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
ES	AR 2	Borison, R.L. et al., Clinical Overview of Risperidone," in: Meltzer, H., Y., ed., <i>Novel Antipsychotic Drugs</i> , Raven Press, Ltd., N.Y.: 233-239 (1992)
ES	AS 2	Chang, R. et al., "Dissolution Characteristics of Polycaprolactone-Polylactide Microspheres of Chlorpromazine," <i>Drug Development and Industrial Pharmacy</i> , Vol. 12, No. 14, 2355-2380 (1986).
ES	AT 2	Chemineer, "Kenics Static Mixers," <i>Bulletin</i> 800: 1-11 (1986).

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EXAMINER INITIALS		DOCUMENT NUMBER	GRANT DATE	NAME	CLASS	SUB-CLASS	FILING DATE
ES	AA3	4,489,055	12/1984	Couvreur et al.	—	—	
	AB3	4,511,258	04/1985	Federighi et al.			
	AC3	4,529,727	07/1985	Kennis et al.			
	AD3	4,530,840	07/1985	Tice et al.			
	AE3	4,542,025	09/1985	Tice et al.			
	AF3	4,585,482	04/1986	Tice et al.			
	AG3	4,614,440	09/1986	King et al.			
	AH3	4,616,937	10/1986	King et al.			
	AI3	4,643,584	02/1987	Allocca et al.			
	AJ3	4,665,075	03/1987	Vandenberk et al.			
ES	AK3	4,675,189	06/1987	Kent et al.	—	—	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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	AM3	EP 0 266 119	05/1988	05/1988 EuroR			<input type="checkbox"/> Yes <input type="checkbox"/> No
	AN3	0368 388	05/1990	Europe			<input type="checkbox"/> Yes <input type="checkbox"/> No
	AO3	WO 90/13361	11/1990	WIPO			<input type="checkbox"/> Yes <input type="checkbox"/> No
ES	AP3	91/13595	09/1991	PCT	—	—	<input type="checkbox"/> Yes <input type="checkbox"/> No

EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)				
ES	AR 3	Chouinard, G. et al., "A Canadian Multicenter Placebo-Controlled Study of Fixed Doses of Risperidone and Haloperidol in the Treatment of Chronic Schizophrenic Patients," <i>Journal of Clinical Psychopharmacology</i> , Vol. 13, No. 1, 25-40 (1993).				
ES	AS 3	Glazer, W.M. et al., "Depot Neuroleptic Therapy: An Underutilized Treatment Option," <i>J. Clin. Psychiatry</i> 53 (12):426-433 (December, 1992).				
ES	AT 3	Heinrich, K. et al., "Experimental Comparison of the Efficacy and Compatibility of Risperidone and Clozapine in Acute Schizophrenia," in: Kane, J.M. (ed), Risperidone: Major Progress in Antipsychotic Treatment. <i>Oxford Clinical Communications</i> , Oxford: 37-39 (1991).				

EXAMINER *theresa bailey* DATE CONSIDERED *01/27/01*

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## U.S. PATENT DOCUMENTS

EXAMINER INITIALS	REF. NO.	DOCUMENT NUMBER	GRANT DATE	NAME	CLASS	SUB-CLASS	FILING DATE
ES	AA1	4,677,191	06/1987	Tankana <i>et al.</i>			
	AB1	4,683,288	07/1987	Tankana <i>et al.</i>			
	AC1	4,689,330	08/1987	Janssen <i>et al.</i>			
	AD1	4,696,258	09/1987	Magrath <i>et al.</i>			
	AE1	4,731,205	03/1988	McNulty <i>et al.</i>			
	AF1	4,737,500	04/1988	Sorg <i>et al.</i>			
	AG1	4,753,535	06/1988	King <i>et al.</i>			
	AH1	4,765,204	06/1988	Buchholz <i>et al.</i>			
	AI1	4,793,713	12/1988	King <i>et al.</i>			
	AJ1	4,798,786	01/1989	Tice <i>et al.</i>			
ES	AK1	4,804,663	02/1989	Kennis <i>et al.</i>			

## FOREIGN PATENT DOCUMENTS

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	AM1	2 246 573	02/1992	United Kingdom			<input type="checkbox"/> Yes <input type="checkbox"/> No
	AN1	0 486 959	05/1992	Europe			<input type="checkbox"/> Yes <input type="checkbox"/> No
	AO1	WO 94/10982	07/1994	WIPO			<input type="checkbox"/> Yes <input type="checkbox"/> No
ES	API	WO 94/25460	11/1994	WIPO			<input type="checkbox"/> Yes <input type="checkbox"/> No

EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
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ES	AS 4	Janssen and Niemegeers, "Chemistry and pharmacology of compounds related to 4-(4-hydroxy-4-phenyl-piperidino)-butyrophenone," <i>Arzneim.-Forsch. (Drug Res.)</i> 12:765-767 (1959).
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ES	AT 4	Janssen, P.A.J. <i>et al.</i> , "Is it Possible to Predict the Clinical Effects of Neuroleptic Drugs (Major Tranquilizers) from Animal Data?," <i>Arzneimit. Forsch. (Drug Res.)</i> 10:1196-1206 (1965).
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EXAMINER	<i>Benach-Sailey</i>	DATE CONSIDERED
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 00166.0051-005		APPLICATION NO. 09/578,908		
		APPLICANT Mesens <i>et al.</i>				OCT 11 2000 PATENT & TRADEMARK OFFICE USA
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## U.S. PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	GRANT DATE	NAME	CLASS	SUB-CLASS	FILING DATE
BS	AA2	4,808,007	02/1989	King <i>et al.</i>	-	-	
	AB2	4,835,139	05/1989	Tice <i>et al.</i>			
	AC2	4,883,666	11/1989	Sabel <i>et al.</i>			
	AD2	4,897,268	01/1990	Tice <i>et al.</i>			
	AE2	4,936,689	06/1990	Federighi <i>et al.</i>			
	AF2	4,940,588	07/1990	Sparks <i>et al.</i>			
	AG2	4,994,281	02/1991	Muranishi <i>et al.</i>			
	AH2	5,008,114	04/1991	Lovrecich			
	AI2	5,075,109	12/1991	Tice <i>et al.</i>			
	AJ2	5,102,872	04/1992	Singh <i>et al.</i>			
BS	AK2	5,158,952	10/1992	Janssen <i>et al.</i>	-	-	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)				
BS	AR 5	Janssen, P.A.J. <i>et al.</i> , "Pharmacology of Risperidone (R 64 766), a New Antipsychotic With Serotonin - S <sub>2</sub> and Dopamine - D <sub>2</sub> Antagonistic Properties," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 244, No. 2, 685-693 (1988).				
BS	AS 5	Koch Engineering Company Inc., "All Mixing Problems Are Not Alike," 1 page, <i>Product Brochure</i> .				
BS	AT 5	Koch Engineering Company Inc., "Static Mixing Technology," Article: 1-15 (1991).				

EXAMINER	<i>Marat Sadek</i>	DATE CONSIDERED	<i>Oct 29/01</i>
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.			

ATTY. DOCKET NO. 00166.0051.605

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FILING DATE May 26, 2000

GROUP 1626

OCT 11 2000

PATENT &amp; TRADEMARK OFFICE

## U.S. PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	GRANT DATE	NAME	CLASS	SUB-CLASS	FILING DATE
G	AA3	5,407,609	04/1995	Tice <i>et al.</i>			
	AB3	5,453,425	09/1995	Francois <i>et al.</i>			
	AC3	5,478,564	12/1995	Wantier <i>et al.</i>			
	AD3	5,650,173	07/1997	Ramstack <i>et al.</i>			
B	AE3	5,792,477	08/1998	Rickey <i>et al.</i>			
	AF3						
	AG3						
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## FOREIGN PATENT DOCUMENTS

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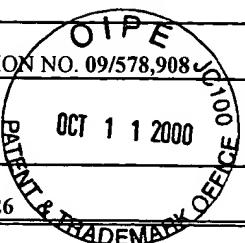
EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
	AR 6	Koflo Corporation, "Static In-Line Mixers," 4 pages, <i>Product Brochure</i>
	AS 6	Komax Systems, Inc., "Triple Action Static Mixers," 2 pages, <i>Product Brochure</i>
G	AT 6	Leysen, J.E., <i>et al.</i> , "Biochemical Profile of Risperidone, a New Antipsychotic," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 247, No. 2, 661-670 (1988).

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EXAMINER INITIALS	REF. NO.		OTHER (Including Author, Title, Date, Pertinent Pages, etc.)				
<i>6</i>	AS	7	Leyson, J.E. <i>et al.</i> , "In vitro receptor binding and neurotransmitter uptake inhibition profile of R 64 766, R 76 477, R 78 543 and 78 544," Janssen Research Foundation, Beerse, Belgium, M 79120, <i>Preclinical Research Report R 64 766/28</i> , 11 pages (January 1991).				
<i>6</i>	AT	7	Maulding, H.V. <i>et al.</i> , "Biodegradable Microcapsules: Acceleration of Polymeric Excipient Hydrolytic Rate By Incorporation of a Basic Medicament," <i>Journal of Controlled Release</i> , 3: 103-117 (1986).				
EXAMINER	<i>Mark Sackey</i>				DATE CONSIDERED <i>10/27/01</i>		
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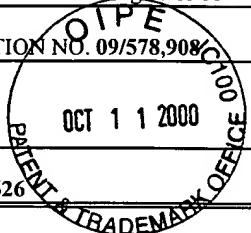
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EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)				
E	AR 8	Megen, A.A.H.P. <i>et al.</i> , "Comparative Pharmacology of Risperidone, Its Major Metabolite R 76 477 <sup>(+)</sup> and the Corresponding Enantiomers R-78-543 <sup>(+)</sup> and R-78-544 <sup>(-)</sup> in Rats and Dogs," Janssen Research Foundation, Beerse, Belgium, N74694, <i>Preclinical Research Report</i> R 64 766/23 (June 1990).				
E	AS 8	Megens, A.A.H.P. <i>et al.</i> , "In Vivo Pharmacological Profile of 9-Hydroxyrisperidone, the Major Metabolite of the Novel Anti and Haloperidol," Janssen Research Foundation, Beerse, Belgium, N 96295, <i>Preclinical Research Report</i> R 64 766/R 76 477 (May 1993).				
E	AT 8	Mertens, C., "Long-term treatment of chronic schizophrenic patients with risperidone," in: Kane, J.M. (ed), Risperidone: Major Progress in Antipsychotic Treatment, <i>Oxford Clinical Communications</i> , Oxford: 44-48 (1991).				

EXAMINER	<i>Benarduckay</i>	DATE CONSIDERED	<i>10/27/01</i>
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AA3						
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EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)				
<i>S</i>	AR 2	Mutsakis <i>et al.</i> , Advances In Static Mixing Technology," <i>Chemical Engineering Progress</i> : 42-48 (July 1986).				
<i>S</i>	AS 9	Niemegeers and Janssen, "A Systemic Study of the Pharmacological Activities of Dopamine Antagonists," in: <i>Life Science</i> 24 (24):2201-2216, Pergamon Press Ltd. (1979).				
<i>S</i>	AT 9	Niemegeers et al., Antiemetic Specificity of Dopamine Antagonists," <i>Psychopharmacology</i> 78:210-213 (1982).				

EXAMINER

*Renata Sackey*

DATE CONSIDERED

*10/27/01*

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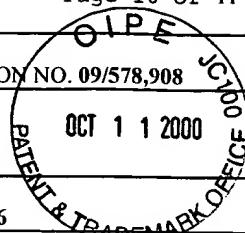
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EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)						
	AS	10	Photocopy of an unofficial English Translation of Japanese Patent Application No. Hei-04 (1992)-332441, "Sustained-Release Microsphere and Process for Producing the Same," filed by Yoshitomi Pharmaceutical Industries, Ltd., which is the priority document of PCT Application No. 94/10982, pp. 1-12.					

	AT	10	Ramtoola, Z., <i>et al.</i> , "Release Kinetics of Fluphenazine from Biodegradable Microspheres," <i>Journal of Microencapsulation</i> , Vol. 8, No. 4, 415-423 (1992).				
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EXAMINER	<i>Marabulosky</i>		DATE CONSIDERED
			10/27/01

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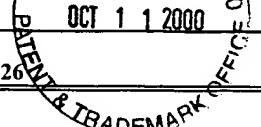
APPLICATION NO. 09/578,908

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENTAPPLICANT Mesens *et al.*

FILING DATE May 26, 2000

GROUP 1626

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## U.S. PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	GRANT DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2						
	AB2						
	AC2						
	AD2						
	AE2						
	AF2						
	AG2						
	AH2						
	AI2						
	AJ2						
	AK2						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2						<input type="checkbox"/> Yes <input type="checkbox"/> No
	AM2						<input type="checkbox"/> Yes <input type="checkbox"/> No
	AN2						<input type="checkbox"/> Yes <input type="checkbox"/> No
	AO2						<input type="checkbox"/> Yes <input type="checkbox"/> No
	AP2						<input type="checkbox"/> Yes <input type="checkbox"/> No

EXAMINER INITIALS	REF. NO.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)				
<i>BS</i>	AR <u>11</u>	Streiff, F., "In-Line Dispersion and Mass Transfer using Static Mixing Equipment," <i>Sulzer Technical Review</i> 3:108-114 (1977).				
<i>BS</i>	AS <u>11</u>	Suzuki, K. <i>et al.</i> , "Microencapsulation and Dissolution Properties of a Neuroleptic in a Biodegradable Polymer, Poly(d,l-lactide)," <i>Journal of Pharmaceutical Sciences</i> , Vol. 74, No. 1, 21-24 (January 1985).				
	AT <u>11</u>					

EXAMINER	<i>Mesens et al.</i>	DATE CONSIDERED	<i>10/27/01</i>

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